MAR 1 9 2004

510(k) Summary
Ceralas D 810 Diode Laser System K032864

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.
Date prepared: March 18, 2004

Name of Device and Name/Address of Sponsor

Ceralas D 810 Diode Laser System
biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser

Predicate Devices

Ceralas D 810 Diode Laser System
Ceralas D 980 Diode Laser System
CardioFocus, Inc.'s Diode Laser System used with CardioFocus, Inc.'s Surgical Lightstic

Intended Use/Indication for Use

The Ceralas D 810 is intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The Ceralas D 810 is generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, and

cardiothoracic surgery. This Ceralas D 810 is specifically indicated for hemostasis or coagulation of soft tissue (including cardiac tissue).

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 601-1; IEC 601-2-22; and EN 60825-1.

Substantial Equivalence

The Ceralas D 810 has the same intended use and the exact same technological characteristics as the previously cleared Ceralas D 810 with the exception of a minor modification to the handpiece for hemostasis or coagulation of cardiac tissue. In addition, all of the Ceralas D 810's general and specific indications for use are cleared indications of at least one of its predicate devices. The Ceralas D 810 also has very similar technological characteristics as its predicate devices. Thus, the Ceralas D 810 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Biolitec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K032864
Trade/Device Name: Cardiac Ceralas D 810 Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II (two)
Product Code: OCL, GEX
Dated: December 22, 2003
Received: December 22, 2003

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of March 19, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

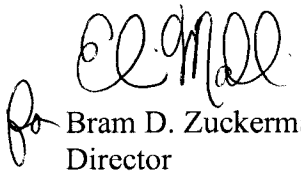
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032864

Device Name: **Ceralas D 810 Diode Laser System**

The Ceralas D 810 is intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The Ceralas D 810 is generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, and cardiothoracic surgery. This Ceralas D 810 is specifically indicated for hemostasis or coagulation of soft tissue (including cardiac tissue).

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____
(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

\\\DC - 61213/0001 - 1783289 v3

510(k) Number K032864